

WE CLAIM:

1. A self-expanding stent for treating a bifurcated vessel having a main vessel and a side branch vessel, comprising:

a cylindrical body having a plurality of rings aligned along a common longitudinal axis, adjacent rings being connected by links, and the cylindrical body having an unexpanded state and an expanded state;

the cylindrical body having a proximal section, a distal section, and a central section;

a number of first peaks in the central section differing from a number of first peaks in the proximal section and the distal section to thereby provide additional material for apposing a side branch vessel; and

the central section first peaks being configured to flare radially outwardly into an opening to the side branch vessel contacting the luminal wall of the side branch vessel and into at least a portion of the side branch vessel;

wherein the cylindrical body self-expands from the unexpanded state to the expanded state.

2. The stent of claim 1, wherein the rings of the proximal section have between four and twelve first peaks, the rings of the distal section have between four and twelve first peaks, and the rings of the central section have between five and fifteen first peaks.

3. The stent of claim 1, wherein the rings of the proximal section have seven first peaks, the rings of the distal section have six first peaks, and the rings of the central section have eight first peaks.

4. The stent of claim 1, wherein the number of first peaks in the ring(s) of the central section is greater than the number of first peaks in any of the rings in either the proximal section or the distal section.
5. The stent of claim 1, wherein the rings are connected by at least one links between adjacent rings.
6. The stent of claim 1, wherein the tubular body has a distal opening, a proximal opening, and a central opening.
7. The stent of claim 6, wherein the distal opening and the proximal opening are aligned along the stent longitudinal axis.
8. The stent of claim 7, wherein the central opening is radially offset relative to the alignment of the distal opening and the proximal opening.
9. The stent of claim 1, wherein the stent is formed from a self-expanding alloy.
10. The stent of claim 9, wherein the self-expanding alloy is nitinol.
11. The stent of claim 1, wherein the stent is coated with at least one layer of a drug.
12. The stent of claim 1, wherein the stent is coated with at least one layer of a therapeutic agent.
13. The stent of claim 1, wherein at least a portion of the stent is coated with at least one layer of a therapeutic agent.

14. The stent of claim 1, wherein at least a portion of the stent is coated with a primer material which adheres to the stent, the primer material being coated with at least one layer of a therapeutic agent or drug.

15. The stent of claim 1, wherein the stent is formed of a superelastic material that enables the central section first peaks to self-expand and flare radially outward to contact the luminal wall of the side branch vessel, and wherein the central section includes a diameter that is larger than a diameter of the proximal section.

16. A method of forming a self-expanding bifurcated stent, comprising:
forming a stent pattern into a single hypotube, the stent pattern including a plurality of rings connected by links, and the stent pattern including a proximal section, a distal section, and a central section having a central opening;
expanding the hypotube to a desired size without expanding the central opening to an angle and annealing the hypotube; and
expanding the central opening to a desired angle and annealing the hypotube.

17. The method of claim 16, wherein the single hypotube is formed of a self-expanding alloy.

18. The method of claim 17, wherein the self-expanding alloy is nitinol.

19. The method of claim 16, wherein expanding the central opening to a desired angle is performed using a mandrel including a ramp.

20. The method of claim 16, wherein expanding the hypotube to a desired size without expanding the central opening, the proximal section and central section are expanded to a diameter larger than a diameter of the distal section and thereby forming a step configuration where the central section abuts the distal section.

21. The method of claim 16, wherein expanding the central opening to a desired angle, the central opening is flared radially outward to an angle that will contact a luminal wall of a side branch vessel when the bifurcated stent self-expands inside a vessel.

22. A method of forming a self-expanding bifurcated stent, comprising:
forming a stent pattern into a single hypotube, the stent pattern including a plurality of rings connected by links, and the stent pattern including a proximal section, a distal section, and a central section having a central opening; and
expanding the hypotube to a desired size and expanding the central opening to a desired angle and annealing the hypotube.

23. The method of claim 22, wherein the single hypotube is formed of a self-expanding alloy.

24. The method of claim 23, wherein the self-expanding alloy is a superelastic alloy.

25. The method of claim 22, wherein annealing the hypotube includes using a mandrel including a ramp to expand the central opening.

26. The method of claim 22, wherein expanding the hypotube to a desired size and expanding the central opening to a desired angle, the proximal section and central section are expanded to a diameter larger than a diameter of the distal section, thereby forming a step configuration where the central section abuts the distal section, and the central opening is flared to an angle that will contact a luminal wall of a side branch vessel when the bifurcated stent self-expands inside a vessel.

27. A method for delivering and implanting a stent in a bifurcated vessel, comprising:

- providing a stent delivery catheter having a stent mounted thereon in a collapsed state, the catheter having an Rx lumen and an Rx guide wire positioned therein and an OTW guide wire lumen and an OTW guide wire positioned therein;
- providing a first delivery sheath over the collapsed stent;
- advancing the catheter and first delivery sheath in a vessel;
- advancing the Rx guide wire into the main vessel to a position distal of the bifurcation;
- advancing the catheter and first delivery sheath over the Rx guide wire to position a distal end of the catheter proximal of the bifurcation;
- advancing the OTW guide wire distally into the side branch vessel;
- advancing the catheter and first delivery sheath distally over the Rx guide wire and the OTW guide wire; and
- removing the first delivery sheath from the stent, allowing the stent to self-expand into an expanded state thereby expanding and implanting the stent to cover a portion of the main vessel and the opening to the side branch vessel.

28. The method of claim 27, further comprising substantially aligning a central opening of the stent with the opening to the side branch vessel before the first delivery sheath is removed from the stent.

29. The method of claim 27, wherein providing a first delivery sheath over the collapsed stent, the first delivery sheath having a slotted edge positioned on the side of a central opening of the stent.

30. The method of claim 29, wherein advancing the OTW guide wire into the side branch vessel, the OTW guide wire lumen includes a tapered tip extending through the slotted edge of the first delivery sheath.

31. The method of claim 30, wherein removing the delivery sheath from stent, the slotted edge of the first delivery sheath tears against the tapered tip of the OTW guide wire lumen.

32. The method of claim 27, further comprising, providing a second delivery sheath disposed over the first delivery sheath, and wherein the second delivery sheath is removed before the first delivery sheath.

33. The method of claim 27, further comprising, providing a second delivery sheath disposed between the first delivery sheath and the stent, the second delivery sheath covering at least a portion of the stent including a central opening.

34. The method of claim 33, further comprising, removing the second delivery sheath from the stent after removing the first delivery sheath from the stent.

35. The method of claim 27, wherein the stent is formed of a self-expanding alloy.
36. The method of claim 27, wherein the self-expanding alloy is nitinol.
37. The method of claim 27, wherein no balloon is required to expand the stent.
38. A stent for treating a bifurcated vessel having a main vessel and a side branch vessel, comprising:
 - a cylindrical body including a superelastic alloy having a plurality of rings aligned along a common longitudinal axis, adjacent rings being connected by links, and the cylindrical body having an unexpanded state and an expanded state; and
 - the cylindrical body having a proximal section, a distal section, and a central section having an opening for apposing a side branch vessel.
39. The stent of claim 38, wherein the central section having a number of first peaks differing from a number of first peaks in the proximal section and the distal section to thereby provide additional material for apposing a side branch vessel.
40. The stent of claim 39, wherein the central section first peaks being configured to flare radially outwardly into an opening to the side branch vessel and into at least a portion of the side branch vessel.
41. The stent of claim 40, wherein the cylindrical body self-expands from the unexpanded state to the expanded state.
42. The stent of claim 39, wherein the cylindrical body is formed from a single hypotube.